



U.S. Department of Justice

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January 5, 2021

BY ECF

The Honorable Mary Kay Vyskocil
United States District Judge
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, New York 10007

Re: *Pfizer Inc. v. United States Department of Health and Human
Services, et al.*, No. 20 Civ. 4920 (MKV)

Dear Judge Vyskocil:

This Office represents the defendants (the “Government”) in the above-referenced action. We write respectfully in light of the supplemental letter brief filed by Plaintiff Pfizer Inc. on December 30, 2020 (ECF No. 58), discussing an HHS-OIG regulation regarding Anti-Kickback Statute (“AKS”) safe harbors (85 Fed. Reg. 77684 (Dec. 2, 2020)), and a recently issued district court opinion discussing the AKS (*United States v. Regeneron Pharma, Inc.*, No. 20 Civ. 11217, 2020 WL 7130004 (D. Mass. Dec. 4, 2020)). See ECF No. 58.

First, Defendants note that Pfizer’s submission should arguably be stricken entirely, given that Pfizer did not observe the Court’s individual practice directing that “[s]ur-reply memoranda will not be accepted without prior permission of the Court.” Moreover, as reflected in Pfizer’s letter (ECF No. 58 at 3), the relevant HHS-OIG regulation and district court opinion were both issued before Pfizer filed its Reply and Opposition Memorandum (ECF No. 53), and therefore could have been discussed therein; Pfizer’s choice not to do so does not warrant a second bite at the apple.

If the Court elects to accept Pfizer’s supplemental submission, Defendants respectfully request the Court’s leave to file a short letter briefly responding to certain characterizations in Pfizer’s letter. Thank you for your consideration of this matter.

Respectfully submitted,

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